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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,220	07/02/2003	H. Garrett Wada	100/07211	7051
21569	7590	01/11/2005	EXAMINER	
CALIPER LIFE SCIENCES, INC. 605 FAIRCHILD DRIVE MOUNTAIN VIEW, CA 94043-2234			DAVIS, DEBORAH A	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 01/11/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/613,220	WADA ET AL.	
	Examin r	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this c mmunication appears n th c ver she t with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10-21-04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' response to the Office Action mailed on April 21, 2004 has been acknowledged. Currently, claims 1-23 are pending and claim 1 have been amended.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-12 and 16-23 rejected under 35 U.S.C. 102(e) as being anticipated by Parce et al (USP#6,046,056).

Parce et al anticipates the instant invention by teaching microfluidic devices comprising first and second parallel microscale channels that are fluidly attached (See Figures 4A-4F). A first microscale channel has a separation region such that compounds that are immobilized on beads are separated by light or acid base prior to flowing the test compound down the reaction channel (column 17, lines 33-61). A second microscale channel contain a particle set such that individual beads settle into a resting well after immobilized test compounds have been released (column 17, lines 33-50). A binding region is within parallel microscale channels such that a test compound will be contacted with a biochemical system for which an effector compound is being

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sought. The biochemical system may be a receptor-ligand mixture, a whole cell or beads that have enzyme/substrate systems immobilized thereon (column 17, lines 62-67 and column 18, lines 1-8). First and second detection regions can be within individual microscale channels such that a soluble signal is flowed out into the reaction channels along the detection channel past the detection window (column 19, lines 35-45). Fluid is controlled by fabricated fluid directions structures such as pumps and valves. More complex systems may be controlled by electroosmotic flow (column 18, lines 1-30). Fluid transport and direction is also accomplished through electrokinesis (column 13, lines 23-30). A microfluidic system may also contain devices that are connected to a computer for implementing operational instructions from the computer and for reporting data from the devices to the computer (column 22, lines 1-32). A detection system can be located adjacent to the detection window to monitor the signal levels (column 19, lines 46-47). A detector adjacent to the detection window monitors the level of fluorescent signal being produced by the enzyme activity on the fluorogenic or chromogenic substrate (column 14, lines 60-65). The test compound can be a variety of compounds such as polysaccharide, biological macromolecules, proteins, naturally occurring or synthetic. A number of solid supports can be made of glass, and polymeric material (column 7, lines 23-45). Separation channels may be treated and filled with high ionic strength buffer to allow separation of test components (column 16, lines 41-55). Figures 4A-4E describe several channels fluidly connected in a parallel fashion, wherein particle-stacking regions are fixed within each channel. Claims 5-7 are concerned with the software programmed to direct the movement of fluid. Parce et al

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discloses that each device is connected to a computer system, which is appropriately programmed to control fluid flow and direction. The computer is programmed to analyze data resulting from the screening assays (column 22, lines 1-25).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parce et al in view of Kurt G. I. Nilsson (USP#5,405,752).

The teaching of Parce et al are set forth above but is silent with respect to specific reagents.

The dependent claims recite avidin and biotin moieties that are not specifically described by the reference, however, the reference of Nilsson discloses the use of enzyme conjugates. Nilsson specifically discloses an avidin-biotin system which improves the sensitivity of an immunoassay. Nilsson discloses that avidin-biotin can be easily coupled to antibodies and other antigens without loss of activity and increased sensitive detection of spectral signals (column 13, lines 52-68).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the reference of Parce et al who recites a variety of reagents that can be used as the test compound or binding moiety to include a avidin and biotin system because they are highly sensitive and well known in the art.

Response to Arguments

7. Applicant's arguments filed October 21, 2004 have been fully considered but they are not persuasive:

8. Applicant's argument that the separation channel taught by Parce et al is not the same as in the instant application and has thus been amended to include that the channel is filled with a separation gel to separate components is noted but not found to be persuasive.

In response, Parce et al teaches a reaction channel that contains a sieving or filtration porous gel (column 18, lines 9-14) that will separate particulate material such as cells from the free fluid flow. Therefore, in the view of the examiner, the above

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teaching appears to meet the newly applied limitation of a gel filled component separation region.

9. Applicant's argument that the reference of Parce et al is improperly applied to the instant application because the reference was commonly owned by the same present assignee, Caliper Technologies Corp. (now Caliper Life Sciences, Inc.) is noted but not found to be persuasive.

In response, this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as Caliper Technologies Corp. at the time this invention was made. Accordingly, Parce et al is disqualified as prior art through 35 U.S.C. 102(f) or (g) in any rejection under 35 U.S.C. 103(a) in this application.

However, this applied art additionally qualifies as prior art under another subsection of 35 U.S.C. 102 and accordingly is ***not disqualified*** as prior art under 35 U.S.C. 103(a).

In the instant case, Parce et al has been applied to the instant filed application under 102(e) and therefore has not been disqualified as 103(a).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Deborah A. Davis

Remsen Bldg.

Room 3D58

January 5, 2005



LONG V. LE

SUPERVISORY PATENT EXAMINER

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01/07/05